



Embera NeuroTherapeutics Announces Successful Completion of Phase 1 Clinical Trial Testing EMB-001, a Potential Novel Treatment for Addictions

-- Embera to Present at the Biotech Showcase in January 2016 --

BOSTON, Mass. and SHREVEPORT, La.—January 6, 2016—[Embera NeuroTherapeutics, Inc.](#), a specialty pharmaceutical company developing novel treatments for cocaine use disorder, smoking cessation, and other addictions, today announced that EMB-001 met the primary endpoints of safety and tolerability in a Phase 1 clinical trial. Embera also announced that the Company’s Chief Executive Officer, Robert Linke and Chief Medical Officer, Dr. Michael Detke, will present at the Biotech Showcase on Monday, January 11, 2016 at 2:30pm in San Francisco, California.

A patented combination of the FDA-approved drugs metyrapone and oxazepam, EMB-001 targets the stress response system as a novel approach to addressing addiction and relapse. The Phase 1 trial was a randomized, double-blind, combined single and multiple rising dose study to evaluate the safety and pharmacokinetics of EMB-001 in healthy adult volunteers who smoke. In each of three cohorts, six subjects received EMB-001 and two received placebo. Subjects received a single dose on the first day, followed by twice daily doses for seven days. The first cohort received the low dose, with increasing doses administered to the second and third cohorts. All daily doses were well below the maximum FDA-approved daily doses for the components, which is consistent with Embera’s hypothesis, supported by published data, that the combination may be more effective than either drug alone in reducing the stress response associated with relapsing in addictions.

The primary endpoints were safety and tolerability. Pharmacokinetics of metyrapone, metyrapol (the primary active metabolite of metyrapone), and oxazepam were measured in plasma. In addition, tobacco use and craving measures were evaluated as exploratory efficacy endpoints. The trial was conducted at Collaborative Neuroscience Network in Long Beach, California and the Pennington Biomedical Research Center in Baton Rouge, Louisiana, with the support of TAB Clinical Trials, a contract research organization based in Cary, North Carolina.

“This is an important clinical milestone for Embera and we are encouraged by the successful completion of this study,” said Michael Detke, M.D., Ph.D., Chief Medical Officer of Embera.

“The success of this study provides a strong rationale for the continued development of EMB-001 for the treatment of substance use disorders, an area in which there are very few treatments either approved or in clinical development.”

Previously, EMB-001 was tested with promising results in a published pilot study in cocaine-dependent human subjects, as well as in published nonclinical models of nicotine, cocaine and methamphetamine dependence. Nearly one million U.S. citizens suffering from cocaine use disorder have no approved treatment option, and current treatment options for tobacco use disorder have limited efficacy and/or pose safety concerns.

“We are proud to be progressing in our mission to address serious needs in addiction disorders,” said Robert Linke, Chief Executive Officer of Embera. “EMB-001 has demonstrated continued promise in the clinic and we look forward to participating at the Biotech Showcase.”

More information about Embera’s Phase 1 clinical trial is available at [Clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02406066) (Identifier: NCT02406066). Detailed Phase 1 results will be presented at a future medical meeting.

About EMB-001

EMB-001 is a patented combination product comprising two FDA-approved medications, the cortisol synthesis inhibitor metyrapone and the benzodiazepine oxazepam. The innovation is based on insights into the physiologic responses to chronic stress in addiction. EMB-001 is thought to act by mechanisms distinct from those of existing addiction treatments and is hypothesized to reduce the increased activity in the stress response system induced by cues that contribute to the acquisition and maintenance of addiction.

EMB-001 may potentially reduce the cravings and loss of control that drive addiction by uniquely targeting multiple pathways, thereby possibly maximizing potential efficacy as well as minimizing safety and tolerability concerns. Therapies that break these barriers and result in long term abstinence and recovery would be significant contributions to the treatment of a broad range of addictions.

About Embera NeuroTherapeutics

Embera NeuroTherapeutics, Inc. is a clinical-stage pharmaceutical company focused on treating a broad range of addictions where the major clinical challenge is a limited range of effective therapies. Embera is developing a novel drug combination (EMB-001) targeting specific brain functions related to stress response that drive craving and relapse associated with these disorders. Embera is advancing EMB-001 development programs in cocaine use disorder and smoking cessation. www.emberaneuro.com

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